NATIONAL GUIDELINE CLEARINGHOUSE™ (NGC)
GUIDELINE SYNTHESIS

ACUTE OTITIS MEDIA

Guidelines

1. American Academy of Pediatrics, American Academy of Family Physicians (AAP/AAFP). Diagnosis and management of acute otitis media. Pediatrics 2004; 113(5):1451-65. [135 references]
2. Cincinnati Children's Hospital Medical Center. Evidence based clinical practice guideline for medical management of acute otitis media in children 2 months to 13 years of age. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2004 Oct. 16 p. [113 references]
3. Scottish Intercollegiate Guidelines Network (SIGN). Diagnosis and management of childhood otitis media in primary care. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2003 Feb. 18 p. (SIGN publication; no.66). [77 references]
4. University of Michigan Health System (UMHS). Otitis media. Ann Arbor (MI): University of Michigan Health System; 2002 May. 12 p. [7 references]

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INTRODUCTION

A direct comparison of American Academy of Pediatrics, American Academy of Family Physicians (AAP/AAFP), Cincinnati Children's Hospital Medical Center (CCHMC), Scottish Intercollegiate Guidelines Network (SIGN), and University of

Michigan Health System (UMHS) recommendations for diagnosing and managing acute otitis media (AOM) in pediatric patients is provided in the tables, below.

The comparison focuses on the appropriate diagnosis and initial treatment of a child presenting with AOM; however, the scope of the guidelines and the populations they consider vary. For example, the AAP/AAFP and CCHMC guidelines address AOM only, while SIGN and UMHS also address otitis media with effusion (OME). The topic of OME is addressed in separate guidelines by AAP/AAFP and CCHMC, and in another synthesis available on the National Guideline Clearinghouse (NGC) Web site.

All four guidelines included in this synthesis focus on the pediatric population. The AAP/AAFP, CCHMC, and UMHS guidelines apply to children age 2 months and older, while SIGN does not specify an age range, targeting children in general. UMHS also briefly addresses otitis media (OM) in adults and infants 0 to 8 weeks old. All four guideline developers note that recommendations concerning children with underlying conditions that increase the risk for AOM or alter its natural course (such as cleft palate, Down syndrome, and immunodeficiencies) are beyond the guideline's scope, although UMHS does briefly discuss the need for referral for these children. Two guidelines also explicitly exclude from consideration additional patient subgroups: AAP/AAFP excludes children with a clinical recurrence of AOM within 30 days, while CCHMC excludes children with pressure equalization (PE) tubes in place. In developing its recommendations, CCHMC considered the conclusions of AAP/AAFP.

Table 1 compares the scope of each of the guidelines. Table 2 compares recommendations for diagnosis, evaluation, and management of AOM in children. Table 3 lists the potential benefits and harms associated with the implementation of each guideline.

Definitions for the levels of evidence used to support the guideline recommendations are given in Table 4; references supporting selected recommendations of the CCHMC guideline are also provided in this table.

Following the content comparison tables, the areas of agreement and differences among the guidelines are discussed

Abbreviations

- AAFP, American Academy of Family Physicians
- AAP, American Academy of Pediatrics
- AOM, acute otitis media
- CCHMC, Cincinnati Children's Hospital Medical Center
- MEE, middle ear effusion
- OM, otitis media
- OME, otitis media with effusion
- PE, pressure equalization
- SIGN, Scottish Intercollegiate Guideline Network
- SNAP, safety-net antibiotic prescription
- UMHS, University of Michigan Health System

TABLE 1: COMPARISON OF SCOPE AND CONTENT	
Objectives	
AAP/AAFP (2004)	To provide recommendations to primary care clinicians for the management of children from 2 months through 12 years of age with uncomplicated AOM
CCHMC (2004)	• To improve the use of appropriate diagnostic criteria • To improve the use of appropriate antibiotic therapy • To improve symptom relief • To avoid medical complications • To improve parental involvement in decision-making around the management of AOM
SIGN (2003)	• To provide recommendations based on current evidence for best practice in the management of AOM and OME • To provide evidence about detection, management, referral, and follow-up of children with AOM and OME Notes: • This guideline excludes discussion of surgical management such as the insertion of grommets and does not address issues beyond childhood years. In addition, the needs of children with genetic or facial abnormalities are not considered. • Recommendations regarding OME are considered in a separate synthesis.
UMHS (2002)	• To limit acute symptoms and suppurative complications caused by OM • To decrease the incidence of hearing loss and its adverse effects on the development of speech and language • To limit the development of antibiotic-resistant bacteria
Target Population	
AAP/AAFP (2004)	• United States • Children from 2 months through 12 years of age with AOM seen in primary care settings
CCHMC (2004)	• United States • Children age 2 months up to 13 years of age who present with signs and symptoms of AOM

	Note: Children with comorbid conditions increasing the risk or severity of otitis media, including immunodeficiencies, craniofacial or neurologic abnormalities, or sensory deficits, are excluded. Children with pressure equalization (PE) tubes in place are also excluded.
SIGN (2003)	• Scotland • Children with AOM or OME Note: The needs of children with genetic or facial abnormalities are not considered.
UMHS (2002)	• United States • Pediatric patients greater than two months old and adults with suspected or confirmed OM (AOM or OME) Note: The guideline also briefly addresses OM in infants 0 to 8 weeks and children with chronic conditions.
Intended Users	
AAP/AAFP (2004)	Advanced Practice Nurses Allied Health Personnel Nurses Physician Assistants Physicians
CCHMC (2004)	Advanced Practice Nurses Allied Health Personnel Health Care Providers Nurses Patients Physician Assistants Physicians
SIGN (2003)	Advanced Practice Nurses Nurses Patients Physician Assistants Physicians Public Health Departments Social Workers Speech-Language Pathologists
UMHS (2002)	Advanced Practice Nurses Nurses Pharmacists Physician Assistants Physicians
Interventions And Practices Considered	

AAP/AAFP (2004)	Diagnosis 1. History and physical examination 2. Diagnostic testing • Otoscopy • Pneumatic otoscopy • Tympanometry • Acoustic reflectometry • Tympanocentesis Treatment/Management 1. Pain management 2. Observation without treatment 3. Antibiotic therapy Education and Prevention 1. Patient/parent education regarding reduction of risk factors Considered but no recommendations offered: • Complementary and alternative medicines (CAM)
CCHMC (2004)	Diagnosis 1. History and physical examination 2. Diagnostic testing • Pneumatic otoscopy • Tympanometry • Acoustic reflectometry Treatment/Management 1. Analgesia for pain (e.g., acetaminophen, ibuprofen, or analgesic ear drops) 2. Observation with or without safety-net antibiotic prescription (SNAP) 3. Antibiotic therapy 4. Follow-up evaluation Consults and Referrals 1. Referral for audiologic evaluation 2. Referral for otolaryngological evaluation Education and Prevention

	1. Educating the family about AOM 2. Educating the family about preventable and non-preventable risk factors Considered but not specifically recommended: • Steroids, antihistamines, decongestants, and complementary or alternative treatments

SIGN (2003)	Diagnosis
	
	1. History and physical examination
	2. Diagnostic testing
	  • Otoscopy
	  • Pneumatic otoscopy
	  • Audiometry
	  • Tympanometry
	
	Treatment/Management
	
	1. Analgesia for pain (i.e., paracetamol)
	2. Observation without antibiotics
	3. Delayed antibiotic therapy
	4. Follow-up evaluation
	
	Consults and Referrals
	
	1. Referral for audiologic evaluation
	2. Referral for otolaryngological evaluation
	
	Education and Prevention
	
	1. Information for parents, teachers, and carers
	2. Advice about risk factors
	
	Considered but recommended against:
	
	• Decongestants, antihistamines, mucolytics, oils
	• Steroids
	
	Considered but no recommendations offered:
	
	• Homeopathy
	
	Note: This guideline also addresses diagnosis and treatment of OME (see related synthesis).

UMHS (2002)	Diagnosis 1. History and physical examination 2. Diagnostic testing • Otoscopy • Pneumatic otoscopy • Tympanometry • Acoustic reflectometry • Tympanocentesis (primarily limited to research settings) Treatment/Management 1. Pain management (e.g., ibuprofen or acetaminophen) 2. Observation without treatment 3. Antibiotic therapy 4. Surgery: tympanostomy tube placement and follow-up; surgery for recurrent AOM 5. Follow up Consults and Referrals 1. Referral for otolaryngological evaluation Education and Prevention 1. Information the patient needs to know 2. Day care, pacifier use, immunizations, xylitol Note: This guideline also addresses incidence of OM and the diagnosis and management of OME in children (see related synthesis).

TABLE 2: COMPARISON OF RECOMMENDATIONS FOR THE DIAGNOSIS, MANAGEMENT, AND PREVENTION OF AOM IN PEDIATRIC PATIENTS	
Definition Of Acute Otitis Media (AOM)	
AAP/AAFP (2004)	A diagnosis of AOM requires 1) a history of acute onset of signs and symptoms, 2) the presence of MEE, and 3) signs and symptoms of middle-ear inflammation. Elements of the definition of AOM are all of the following: 1. Recent, usually abrupt, onset of signs and symptoms of middle-ear inflammation and MEE 2. The presence of MEE that is indicated by any of the following: a. Bulging of the tympanic membrane

	b. Limited or absent mobility of the tympanic membrane c. Air-fluid level behind the tympanic membrane d. Otorrhea 3. Signs or symptoms of middle-ear inflammation as indicated by either: a. Distinct erythema of the tympanic membrane, or b. Distinct otalgia (discomfort clearly referable to the ear[s] that results in interference with or precludes normal activity or sleep)
CCHMC (2004)	Definitions used in this guideline: • AOM: MEE with rapid onset of one or more of the following: otalgia, ear pulling, otorrhea, fever, irritability, anorexia, vomiting, or other symptoms • Sporadic AOM: AOM occurring more than 3 months after a prior episode of AOM • Recurrent AOM (otitis-prone condition): History of 6 episodes over a 12-month period, taking into account the severity of episodes, clustering of episodes, and persistence of OME Requirements for diagnosis of AOM: 1. History of acute onset of signs and symptoms 2. Presence of MEE indicated by one of the following: • Bulging tympanic membrane • Decreased mobility of tympanic membrane (ear drum) • Discharge from the ear (otorrhea) 3. Signs and symptoms of ME inflammation indicated by either: • Red tympanic membrane, or • Discomfort affecting normal activity and/or sleep (earache, otalgia)
SIGN (2003)	The working definition of AOM in this Guideline is inflammation of the middle ear of rapid onset presenting most often with local symptoms (the two most common being earache and rubbing or tugging of the affected ear) and systemic signs (fever, irritability, and poor sleep, for example). There may be a preceding history of upper respiratory symptoms including cough and rhinorrhea.
UMHS (2002)	• MEE — demonstrated by pneumatic otoscopy, tympanometry, air fluid level, or a bulging tympanic membrane plus • Evidence of acute inflammation — opaque, white, yellow, or erythematous tympanic membrane or purulent effusion

	plus • Symptoms of otalgia, irritability, or fever
Diagnosis Of AOM	
AAP/AAFP (2004)	• To diagnose AOM, the clinician should confirm a history of acute onset, identify signs of MEE, and evaluate for the presence of signs and symptoms of middle-ear inflammation. (Recommendation) Children with AOM usually present with a history of rapid onset of signs and symptoms such as otalgia (or pulling of the ear in an infant), irritability in an infant or toddler, otorrhea, and/or fever. These findings, other than otorrhea, are nonspecific and frequently overlap those of an uncomplicated viral upper respiratory infection. Other symptoms of a viral upper respiratory infection, such as cough and nasal discharge or stuffiness, often precede or accompany AOM and are nonspecific also. Accordingly, clinical history alone is poorly predictive of the presence of AOM, especially in younger children. The presence of MEE is commonly confirmed with the use of pneumatic otoscopy but can be supplemented by tympanometry and/or acoustic reflectometry. MEE also can be demonstrated directly by tympanocentesis or the presence of fluid in the external auditory canal as a result of tympanic membrane perforation. • If the patient fails to respond to the initial management option within 48 to 72 hours, the clinician must reassess the patient to confirm AOM and exclude other causes of illness. (Recommendation)
CCHMC (2004)	General • Signs and symptoms of AOM are often nonspecific and overlap with those of upper respiratory infections. Clinical diagnosis is especially less reliable in the child under 2 years of age. This contributes to difficulty in accurately diagnosing AOM and in evaluating results of clinical trials (Dagan & McCracken, 2002 [S]; Froom et al., 1990 [O]; Wald, 2003 [E]). History and Physical Examination • It is recommended that the components to assess for AOM in the history and physical include history of acute onset of

	symptoms, presence of MEE, and signs and symptoms of middle ear inflammation (American Academy of Pediatrics [AAP] Subcommittee, 2004 [S]). (See table titled "Requirements for Diagnosis of AOM" under "Definition of Acute Otitis Media (AOM)," above.) • It is recommended that pneumatic otoscopy and/or tympanometry be used to enhance accuracy when diagnosing AOM (Spiro et al., 2004 [A]; Karma et al., 1989 [D]; Brookhouser, 1998 [S]; Pelton, 1998 [S]; Jones & Kaleida, 2003 [O]; Pichichero, 2002 [O]; Pichichero & Poole, 2001 [O]). Note: Acoustic reflectometry is not often used nor readily available in the Cincinnati area, though the procedure is acceptable for determining the presence of MEE (Block et al., 1999 [C]; Barnett et al., 1998 [C]; Block et al., 1998 [C]; Kimball, 1998 [S]). • It is recommended that ear pain (otalgia) be assessed, as determined by discomfort affecting normal activity and/or sleep (Kontiokari et al., 1998 [C]; "The assessment and management," 2001 [S]). • It is recommended that, for patients with recurrent AOM, additional attention be paid to parental concerns about hearing loss, speech delay, or language delay (Roberts, Rosenfeld, & Zeisel, 2004 [M]).
SIGN (2003)	• AOM is a purulent middle ear process and, as such, otoscopic signs and symptoms consistent with a purulent MEE in association with systemic signs of illness are required. Ear related symptoms may include earache, tugging or rubbing of the ear, irritability, restless sleep, and fever. Children may also have a history of cough and rhinorrhea, symptoms which are reported to increase the risk of AOM. Earache, however, is the single most important symptom. (Evidence level 2+,3,4) • Otoscopic appearances typical of AOM include bulging tympanic membrane with loss of the normal landmarks, change in colour (typically red or yellow), and poor mobility. (Evidence level 2+) • Systemic signs of illness with a MEE are not sufficient to make the diagnosis, and similarly neither is the finding of an incidental effusion in an otherwise well patient. • It should be borne in mind that the typical symptoms and signs (see Table 1 in the original guideline document) may have resolved by perforation of the tympanic membrane and discharge of pus. Additionally, AOM may leave a MEE for a variable period of time following resolution of the acute symptoms - the two forms of otitis media should be considered part of a disease continuum. (Evidence level 1+,4)
UMHS	• Distinguish between AOM and OME in making therapeutic

(2002)	decisions.
	• AOM:
	  • MEE — demonstrated by pneumatic otoscopy, tympanometry, air fluid level, or a bulging tympanic membrane plus
	  • Evidence of acute inflammation — opaque, white, yellow, or erythematous tympanic membrane or purulent effusion plus
	  • Symptoms of otalgia, irritability, or fever
	• The presence of MEE should be determined by the combined use of otoscopy, pneumatic otoscopy, and tympanometry when necessary [D].

Observation Without Treatment In Patients With AOM	
AAP/AAFP (2004)	• Observation without use of antibacterial agents in a child with uncomplicated AOM is an option for selected children based on diagnostic certainty, age, illness severity, and assurance of follow-up. (Option) • If the patient fails to respond to the initial management options within 48 to 72 hours, the clinician must reassess the patient to confirm AOM and exclude other causes of illness. If AOM is confirmed in the patient initially managed with observation, the clinician should begin antibacterial therapy. (Recommendation)
CCHMC (2004)	AOM is a disease with a high spontaneous resolution rate (78 to 80% resolve within 7 to 14 days), and routine antibiotic therapy of all children with suspected AOM results in the treatment of many children in whom there may be either modest benefit and/or modest adverse outcomes from antibiotic therapy (Glasziou et al., 2003 [M]; Marcy et al., 2001 [M]; Rosenfeld et al., 1994 [M]; Dowell et al., "Otitis media," 1998 [S]). Moreover, the decision to use antibiotics and the specific choice of antibiotics must take into account the increasing emergence of bacterial resistance (Doern et al., 1998 [C]; Jacobs et al., 2003 [O]; Mason et al., 2003 [O]). Note: While it is suggested in general that children under two years of age with AOM be treated with antibiotics, it is recognized that in certain situations observation without antibiotics or with a safety-net antibiotic prescription (SNAP) may be reasonable. (See Table 5 in original guideline.) If observation or SNAP is utilized, both the clinician and the parents are advised to be aware of the higher relapse/recurrence rate in this age group, and close follow-up must be assured (Siegel et al., 2003 [C]). • It is recommended that in children over age 2 years with AOM

	and who are well-appearing the treatment options be discussed with the family and that the family be involved in the decision making. The options include: • Treatment with a SNAP to be filled after 48 to 72 hours if symptoms do not resolve with observation • Treatment with a 5-day course of antibiotics (see treatment recommendation #2 and Table 4 in the original guideline document for discussion of antibiotic selection and doses) Note 1: There is inadequate evidence to say that antibiotic therapy is or is not beneficial to most children with AOM (Wald, 2003 [E]). Note 2: No antibiotic prescription, with follow-up within 48 to 72 hours, is also an option in the specific case when a practitioner would like to control the observation option more closely.
SIGN (2003)	• Children diagnosed with AOM should not routinely be prescribed antibiotics as the initial treatment. (Grade B) • Delayed antibiotic treatment (antibiotic to be collected at parents' discretion after 72 hours if the child has not improved) is an alternative approach which can be applied in general practice. (Grade B)
UMHS (2002)	• Antibiotic therapy can be deferred for many asymptomatic patients, and for most cases of OME [D]. Based on the review of the evidence described in the original guideline, UMHS notes that data support a strategy of deferring routine antibiotic therapy for asymptomatic patients or older patients with mild symptoms, or in patients in whom symptoms of AOM are overshadowed by symptoms of viral illness such as gingivostomatitis or gastroenteritis ("incidental AOM"). These individuals should be followed for clearance of effusion, and antibiotic therapy should be initiated if symptoms worsen.
Use Of Analgesics In Patients With AOM	
AAP/AAFP (2004)	• The management of AOM should include an assessment of pain. If pain is present, the clinician should recommend treatment to reduce pain. (Strong Recommendation) • The clinician should select a treatment based on a consideration of benefits and risks and, when possible, incorporate parent or caregiver and patient preference: • Acetaminophen, ibuprofen* • Effective analgesia for mild to moderate pain. Readily available. Mainstay of pain management

	for AOM.
	• Home remedies (distraction, external application of heat or cold, oil)
	  • No controlled studies that directly address effectiveness
	  • May have limited effectiveness
	• Topical agents (benzocaine [Auralgan®, Americaine Otic®] and naturopathic agents [Otikon Otic Solution®])
	  • Additional, but brief, benefit over acetaminophen in patients older than 5 years
	  • Comparable to ametocaine/phenazone drops (Anaesthetic®) in patients older than 6 years
	• Homeopathic agents
	  • No controlled studies that directly address pain.
	• Narcotic analgesia with codeine or analogs
	  • Effective for moderate or severe pain. Requires prescription, risk of respiratory depression, altered mental status, gastrointestinal upset, and constipation.
	• Tympanostomy/myringotomy
	  • Requires skill and entails potential risk
	
	*See Note at end of synthesis.

CCHMC (2004)	• It is recommended that all children with AOM who have a positive assessment for pain be treated with an appropriate analgesic (AAP Subcommittee, 2004 [S]; "The assessment and management," 2001 [S]). Note 1: Ear pain in AOM is self-limiting and time is the greatest factor in pain reduction (Sarrell, Cohen, & Kahan, 2003 [A]). Therefore, the immediate availability of a safe and effective analgesic is more important than which agent is used. These include oral agents (acetaminophen or ibuprofen*) or topical ear drops (anesthetic or Naturopathic Herbal Extract Ear Drops) (Perrott et al., 2004 [M]; Sarrell, Cohen, & Kahan, 2003 [A]; Sarrell, Mandelberg, & Cohen, 2001 [A]; Bertin et al., 1996 [A]; Hoberman et al., "Efficacy of Auralgan," 1997 [B]; "The assessment and management," 2001 [S]). Note 2: In patients with a perforated eardrum and/or discharge from the ear, avoid topical analgesic ear drops as their use will likely result in severe dizziness and vomiting. *See Note at end of synthesis.
SIGN (2003)	• Parents should give paracetamol for analgesia but should be advised of the potential danger of overuse. (Grade D) • Insertion of oils should not be prescribed for reducing pain in

	children with AOM. (Grade B)
UMHS (2002)	• Ibuprofen* or acetaminophen to control pain *See Note at end of synthesis.
Antimicrobial Therapy In Patients With AOM	
AAP/AAFP (2004)	• If a decision is made to treat with an antibacterial agent, the clinician should prescribe amoxicillin for most children. (Recommendation) • When amoxicillin is used, the dose should be 80 to 90 mg/kg/day. (Option) • If the patient fails to respond to the initial management option within 48 to 72 hours, the clinician must reassess the patient to confirm AOM and exclude other causes of illness. If AOM is confirmed in the patient initially managed with observation, the clinician should begin antibacterial therapy. If the patient was initially managed with an antibacterial agent(s), the clinician should change the antibacterial agent(s). (Recommendation) See Table 6 in the original guideline document for recommended antibacterial agents for patients who are being treated initially with antimicrobial agents or have failed 48 to 72 hours of observation or initial management with antimicrobial agents.
CCHMC (2004)	• It is recommended that treatment with a 10-day course of antibiotics be given to children less than 2 years of age with AOM (Cohen et al., 2000 [A], 1998 [A]; AAP Subcommittee, 2004 [S]). Amoxicillin, in the dose range of 80 to 90 mg/kg/day, is effective in the treatment of a first episode of AOM or for a recurrence more than 1 month since recovery from a prior episode of AOM (Rosenfeld et al., 1994 [M]; Piglansky et al., 2003 [C]; AAP Subcommittee, 2004 [S]). (See Table 4 in original guideline document for recommended doses for first-line therapy). In cases when the clinician has a high suspicion for concurrent conjunctivitis-otitis media syndrome, commonly caused by a beta-lactamase producing organism, it is reasonable to consider a second-line antibiotic (Wald, 1997 [S]). For children with allergies to penicillin, or other reasons to consider alternative antibiotics, consider a second-line antibiotic. In a child less than 1 year of age with a history of a penicillin allergy, a careful review of the reported reaction is prudent (Rosenfeld et al., 1994 [M]). [NGC note: see extended list of antibiotic options, dosages, and preparations in Appendix

3 of original guideline].

Note: While it is suggested in general that children under two years of age with AOM be treated with antibiotics, it is recognized that in certain situations observation without antibiotics or with a SNAP may be reasonable. (See Table 5 in original guideline document concerning SNAP definition and management.) If observation or SNAP is utilized, both the clinician and the parents are advised to be aware of the higher relapse/recurrence rate in this age group, and close follow-up must be assured (Siegel et al., 2003 [C]).

- It is recommended that in children over age 2 years with AOM and who are well-appearing, that the treatment options be discussed with the family and that the family be involved in the decision making. The options include:
    - Treatment with a SNAP to be filled after 48 to 72 hours if symptoms do not resolve with observation.
    - Treatment with a 5-day course of antibiotics (See treatment recommendation 2 and Table 4 in the original guideline document for discussion of antibiotic selection and doses)

      Note 1: There is inadequate evidence to say that antibiotic therapy is or is not beneficial to most children with AOM (Wald, 2003 [E]).

      Note 2: No antibiotic prescription, with follow-up within 48 to 72 hours, is also an option in the specific case when a practitioner would like to control the observation option more closely.

- It is recommended that children over age 2 years with AOM and with severe illness (see Table 6 in original guideline document) be treated with a 5-day course of antibiotics (See treatment recommendation 2 and Table 4 in the original guideline document for discussion of antibiotic selection and doses) (Kozyrskyj et al., 2000 [M], 1998 [M]).
- It is recommended, for a child with a recurrence of AOM in less than 1 month from completion of antibiotic therapy from a prior episode of AOM, or for a child who has recently been on antibiotics for other reasons, that antibiotic choices other than amoxicillin be considered (Leibovitz et al., 2003 [C]; Carlin et al., 1987 [C]; Dowell et al., "Principles of judicious use," 1998 [S]; Klein, 1998 [S]). (For an extended list of antibiotic options, doses, and preparations, see Appendix 3 of the original guideline document.)

  Note: There is no strong evidence to support prolonged or prophylactic antibiotic therapy in recurring AOM (Williams et al., 1993 [M]; Koivunen et al., 2004 [A]). Persistent MEE is

	common, and parents may be counseled to expect fluid to take several weeks to months to clear (Rosenfeld & Kay, 2003 [M]; AAP Subcommittee, 2004 [S]). • It is recommended, for the first or a sporadic episode of AOM, that when the initial management approach fails, the clinician reevaluate the antibiotic decision. If symptoms worsen at any time or if symptoms do not improve during a waiting period of 48 to 72 hours of initial presentation with AOM, and reexamination continues to suggest that AOM is the appropriate diagnosis, then start amoxicillin if not already initiated or change to an alternative antibiotic if the child is already on a first line drug. Note: Options for alternative antibiotics include: • Amoxicillin/clavulanate: efficacy has been shown for AOM and may be used when resistance is likely (Hoberman et al., "Equivalent efficacy," 1997 [A]; Dagan et al., 2001 [C]) • Ceftriaxone intramuscularly (IM): 3 consecutive daily doses is efficacious in nonresponsive AOM for children with vomiting or otherwise unable to tolerate oral dosing (Leibovitz et al., 2000 [A]). For children with allergies to penicillin, or other reasons to consider another antibiotic choice, see extended list of antibiotic options, doses, and preparations in Appendix 3 of the original guideline document.
SIGN (2003)	• If an antibiotic is to be prescribed, the conventional five day course is recommended at dosage levels indicated in the British National Formulary. (Grade B) With Streptococcus pneumoniae and Haemophilus influenzae, broad spectrum antibiotics such as amoxicillin, or amoxicillin with clavulanic acid, are the drugs of choice if an antibiotic is to be used. Cefaclor, cotrimoxazole, trimethoprim and erythromycin can be effective, but are less safe than amoxicillin.
UMHS (2002)	• For isolated symptomatic episodes of AOM, the antibiotic of choice is amoxicillin (at a dose of 60 to 90 mg/kg/day, divided dosing twice a day [div b.i.d.] for 5 to 10 days). Treat AOM that is clinically unresponsive to amoxicillin after 72 hours of therapy with high-dose amoxicillin/clavulanate [C]. Patients with persistent symptoms on high-dose amoxicillin/clavulanate should receive 1 to 3 doses of IM ceftriaxone [C]. • The use of macrolides for AOM should be avoided [B]. • Avoid multiple courses of empiric broad-spectrum antibiotics

	[B]. • Routine prophylactic antibiotic therapy is not recommended for recurrent AOM. Management of all children with AOM: • Uncomplicated AOM with symptoms (usually due to viruses, S. pneumoniae, H. influenzae, or Moraxella catarrhalis). A single course of high dose amoxicillin. If symptoms persist at 72 hours, use a single course of high dose amoxicillin/clavulanic acid (A/C). Cefuroxime axetil, cefpodoxime proxetil, and cefdinir are alternative second line agents. If symptoms persist for several more days, consider 1 to 3 doses of IM ceftriaxone. Trimethoprim/sulfamethoxazole, azithromycin, and cefprozil are acceptable for children with allergy to amoxicillin. Antibiotics should be given for 10 days for infants and toddlers and for 5 days for age 2 and up. Note: See Table 2 in the original guideline document for management of AOM with significant systemic toxicity, AOM with conjunctivitis, AOM with bronchitis, AOM with bronchiolitis, and purulent otorrhea.
Patient Education And Preventive Counseling In AOM	
AAP/AAFP (2004)	• Clinicians should encourage the prevention of AOM through reduction of risk factors. (Recommendation) During infancy and early childhood, reducing the incidence of respiratory tract infections by altering child care center attendance patterns can reduce the incidence of recurrent AOM significantly. The implementation of breastfeeding for at least the first 6 months also seems to be helpful against the development of early episodes of AOM. Avoiding supine bottle feeding ("bottle propping"), reducing or eliminating pacifier use in the second 6 months of life, and eliminating exposure to passive tobacco smoke have been postulated to reduce the incidence of AOM in infancy; however, the utility of these interventions is unclear.

CCHMC (2004)	• It is recommended that the family be educated regarding the natural history of AOM, signs and symptoms of clinical deterioration, and appropriate follow-up.
	• It is recommended that the practitioner discuss with the parent that persistent MEE is common, and parents may expect fluid to take several weeks to months to clear (Rosenfeld & Kay, 2003 [M]; AAP Subcommittee, 2004 [S]).
	• It is recommended that the family be educated about preventable risk factors. These include:
	  • Exposure to others (especially family members) with upper respiratory tract infections (Uhari, Mantysaari, & Niemela, 1996 [M])
	  • Parental smoking or other sources of second-hand

	smoke (Uhari, Mantysaari, & Niemela, 1996 [M]; Ilicali et al., 1999 [C]) • Daycare attendance (Uhari, Mantysaari, & Niemela, 1996 [M]; Bradley, 2003 [C]) • Note: Though daycare attendance may not be preventable, options to reduce risk of AOM include delaying daycare, selecting a setting with fewer children, and/or verifying the daycare facility's hand washing practices and availability of sinks. • Excessive pacifier use, limiting use to when the child is falling asleep (Uhari, Mantysaari, & Niemela, 1996 [M]; Niemela et al., 2000 [A]) • Breastfeeding duration less than 3 months (Uhari, Mantysaari, & Niemela, 1996 [M]) • Bottlefeeding with the child on his/her back: assure that infants are offered bottle feedings while sitting in upright positions (Tully, Bar-Haim, & Bradley, 1995 [B] Parents may also benefit by understanding nonpreventable risk factors or common misconceptions. • Anatomy of the eustachian tube in young children • It is not always known why a child gets AOM. • Allergies do not cause AOM.
SIGN (2003)	No specific recommendations are given for patient education or preventive counseling for AOM.
UMHS (2002)	• Offer annual influenza vaccination to all children with a history of recurrent AOM [A]. • Ensure that all infants received the recommended pneumococcal conjugate vaccine [A]. • Avoid exposure to environmental smoke and group daycare (when feasible) for children with recurrent AOM or OME [C]. • Discontinue pacifier use in children with recurrent AOM and OME. Consider xylitol syrup or xylitol-containing chewing gum for children with recurrent AOM, depending on age [A]. Additionally, a section titled "Information the Patient Needs to Know" is provided in the original guideline document.
Recommendations For Referral	
AAP/AAFP (2004)	No recommendations offered
CCHMC (2004)	• It is recommended that a practitioner have a low threshold for referral for an audiologic evaluation by a pediatric audiologist if

	concerns around hearing, speech, or language are raised by parents, clinician, or other caregivers because of recurrent AOM (Mandel et al., 1991 [A]; Hsu, Levine, & Giebink, 1998 [C]; Teele et al., 1990 [C]; Bachmann & Arvedson 1998 [S]).
	• It is recommended that a child be referred for an otolaryngological evaluation for:
	  • Recurrent AOM (history of 6 episodes over a 12-month period taking into account the severity of episodes, clustering of episodes, and persistence of OME)
	  • Persistent otorrhea
	  • Concerns about mastoiditis, or other complications of AOM
	  • Perceived need for tympanocentesis and/or myringotomy (e.g., acute episode not responsive to medical therapy)
	  • Abnormal audiologic evaluation
	
	(Froom et al., 1993 [C])

SIGN (2003)	• Children who require hearing loss assessment should be referred to an audiologist (Good practice point). • Children with frequent episodes (more than four in six months) of AOM, or complications, should be referred to an otolaryngologist (Grade D). • Complications of AOM such as mastoiditis or facial nerve paresis require referral.

UMHS (2002)	• Clinical situations meriting consideration of subspecialty consultation or referral (Note: In many cases, primary care physicians will be able to manage these conditions without referral)
	  • AOM
	  • Emergent/Urgent referral. Any suspected complications such as meningitis (medical emergency) or other intracranial complications, facial weakness or paralysis, vertigo, or post-auricular swelling, redness, or displacement of the auricle (mastoiditis).
	  • Note: Fluid in the mastoid air cells on computed tomography scan or x-ray, without clinical evidence of mastoiditis, is common with AOM and is not, in itself, an indication for referral.
	  • Semi-urgent referral (2 to 3 days): Failure of antibiotic therapy with persistent severe signs and symptoms of AOM such as high fever or intractable pain (for consideration of diagnostic tympanocentesis).
	  • Non-urgent referral: Perforation with persistent otorrhea.

	• Recurrent AOM (see Table 7 in the original guideline document) • Other (see Table 7 in the original guideline document)
Use Of Complementary And Alternative Medicine For AOM	
AAP/AAFP (2004)	There is insufficient evidence to make a recommendation regarding the use of complementary and alternative medicine for AOM. (No Recommendation)
CCHMC (2004)	It is not recommended that other therapies be used in the treatment of AOM (AAP 2004[S]). Note: Steroids, antihistamines, decongestants, and complementary or alternative treatments have not been documented to be efficacious in the treatment of AOM (Butler & Van Der Voort, 2002 [M]; Flynn, Griffin, & Tudiver, 2002 [M]; Barnett et al., 2000 [C]; AAP Subcommittee, 2004 [S]. Antihistamines may prolong the duration of MEE. Note: It is recognized that use of complementary and alternative medicine (CAM) is common and its use is often not reported to the primary care physician (PCP) (Eisenberg et al., 1998 [O], Spigelblatt et al., 1994 [O]). The PCP may take the AOM visit as an opportunity to begin a respectful discussion regarding the safety and efficacy of CAM with families who report its use.
SIGN (2003)	While homeopathy was considered, due to lack of evidence, no recommendation can be made at this time.
UMHS (2002)	No recommendations offered

TABLE 3: BENEFITS AND HARMS	
Benefits	
AAP/AAFP (2004)	• Appropriate diagnosis and initial treatment of a child presenting with AOM • Improved adherence to a consistent definition of AOM • Appropriate use of antibacterial agent(s) including improved decision making when an alternative to amoxicillin is indicated
CCHMC	• Effective medical management of AOM in children 2 months to

(2004)	13 years of age • Improved use of appropriate diagnostic criteria • Improved use of appropriate antibiotic therapy • Improved symptom relief • Avoidance of medical complications • Improved parental involvement in decision-making around the management of AOM
SIGN (2003)	• Antibiotics in comparison to placebo and observational treatment may have a modest benefit on symptom resolution and failure rates, as variously defined, in children over the age of two years with AOM. The available evidence on natural history of AOM shows that in studies with close follow up, very few episodes of mastoiditis or other suppurative complications are reported in children with AOM not initially treated with antibiotics.
UMHS (2002)	• Appropriate use of diagnostic techniques and management options for children with otitis media • Improved control of acute symptoms and suppurative complications of otitis media • Decreased incidence of hearing loss and resulting speech and language delays • Decreased development of antibiotic resistance
Harms	
AAP/AAFP (2004)	General Antibiotic Therapy • Antibacterial agent treatment might mask mastoiditis signs and symptoms, producing a subtle presentation that can delay diagnosis. • Antibiotics may lead to diarrhea, rash, anaphylaxis, and symptoms of hematologic, cardiovascular, central nervous, renal, hepatic, and respiratory systems. • Antimicrobial drug resistance may increase with increased use of antibiotics. Analgesic Therapy • Narcotic analgesia with codeine or analogs has a risk of respiratory depression, altered mental status, gastrointestinal upset, and constipation.
CCHMC (2004)	None stated

SIGN (2003)	Analgesic Therapy • Although non-steroidal anti-inflammatory drugs (NSAIDs) are frequently used by parents, caution should be exercised because of the side effect profile.
UMHS (2002)	Diagnostic Procedures • Tympanocentesis is a painful procedure, and, like any invasive technique, presents a risk for complications. General Antibiotic Therapy • Side effects are primarily gastrointestinal (5% to 20%) and cutaneous (allergic and diaper rash) (3% to 10%). • Can mask serious infectious disease complications requiring specific therapy (partially treated meningitis; recurrent urinary tract infections). • The increasing prevalence of antibiotic-resistant bacteria is an ever-present concern. Trimethoprim/Sulfamethoxazole • Can be associated with aplastic anemia and Stevens-Johnson Syndrome. Xylitol-Containing Chewing Gum • Risk of choking, especially in younger children.

TABLE 4: EVIDENCE RATING SCHEMES AND REFERENCES	
AAP/AAFP (2004)	Recommendations Rating Scheme: Strong Recommendation - A strong recommendation in favor of a particular action is made when the anticipated benefits of the recommended intervention clearly exceed the harms (as a strong recommendation against an action is made when the anticipated harms clearly exceed the benefits) and the quality of the supporting evidence is excellent. In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an

	alternative approach is present. Recommendation - A recommendation in favor of a particular action is made when the anticipated benefits exceed the harms, but the quality of evidence is not as strong. Again, in some clearly identified circumstances, recommendations may be made when high-quality evidence is impossible to obtain but the anticipated benefits outweigh the harms. Clinicians would be prudent to follow a recommendation, but should remain alert to new information and sensitive to patient preferences. Option - Options define courses that may be taken when either the quality of evidence is suspect or carefully performed studies have shown little clear advantage to one approach over another. Clinicians should consider the option in their decision making, and patient preference may have a substantial role. No Recommendation - No recommendation indicates that there is a lack of pertinent published evidence and that the anticipated balance of benefits and harms is presently unclear. Clinicians should be alert to new published evidence that clarifies the balance of benefit versus harm.
CCHMC (2004)	The type of evidence is identified and classified for each recommendation using the following scheme: Evidence Based Grading Scale A: Randomized controlled trial: large sample B: Randomized controlled trial: small sample C: Prospective trial or large case series D: Retrospective analysis E: Expert opinion or consensus F: Basic laboratory research S: Review article M: Metal analysis Q: Decision analysis L: Legal requirement O: Other evidence X: No evidence References Supporting the Recommendations • American Academy of Pediatrics Subcommittee on Management of Acute Otitis Media. Diagnosis and management of acute otitis media. Pediatrics 2004 May;113(5):1451-65. PubMed • Bachmann KR, Arvedson JC. Early identification and intervention for children who are hearing impaired. Pediatr Rev 1998 May;19(5):155-65. [7 references] PubMed • Barnett ED, Klein JO, Hawkins KA, Cabral HJ, Kenna M, Healy

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SIGN (2003)	Grades of Recommendations A - At least one meta-analysis, systematic review of randomised controlled trials (RCTs), or randomised controlled trial rated as 1++ and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results B - A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or

	Extrapolated evidence from studies rated as 1++ or 1+ C - A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++ D - Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+ Levels of Evidence 1++ - High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias 1+ - Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias 1- - Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias 2++ - High quality systematic reviews of case control or cohort studies. High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal 2+ - Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal 2- - Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal 3 - Non-analytic studies, e.g., case reports, case series 4 - Expert opinion
UMHS (2002)	Levels of Evidence: Levels of evidence reflect the best available literature in support of an intervention or test. A. Randomized controlled trials B. Controlled trials, no randomization

	C. Observational trials D. Opinion of expert panel

GUIDELINE CONTENT COMPARISON

The American Academy of Pediatrics/American Academy of Family Physicians (AAP/AAFP), Cincinnati Children's Hospital Medical Center (CCHMC), Scottish Intercollegiate Guidelines Network (SIGN), and University of Michigan Health System (UMHS) present recommendations for the diagnosis and management of AOM in pediatric patients based on evidence available at the time of each report and provide explicit reasoning behind their judgments, ranking the level of evidence for each major recommendation. CCHMC also offers literature citations to support its major recommendations. UMHS provides the rationale for several of its recommendations in narrative form.

Each guideline develops a working definition for AOM, but the focus of the guidelines and their respective target populations vary. For example, the AAP/AAFP and CCHMC guidelines are limited to a discussion of recommendations for the diagnosis and treatment of uncomplicated AOM, with both groups presenting recommendations for OME in separate guidelines. The SIGN and UMHS guidelines consider the diagnosis and treatment of both AOM and OME. In addition, UMHS considers the management of recurrent AOM. While AAP/AAFP, CCHMS, and SIGN limit their recommendations to pediatric patients, UMHS provides recommendations for both children and adults with AOM.

Areas of Agreement

Diagnosis of AOM

AAP/AAFP, CCHMC, SIGN, and UMHS are in general agreement regarding the definition and requirements for diagnosing AOM. All of the groups agree that the diagnosis of AOM should be based on an acute onset of signs and symptoms (e.g., earache, tugging of the ears, irritability, fever), evidence of MEE (e.g., bulging of the tympanic membrane, limited or absent mobility of the tympanic membrane), and evidence of acute inflammation (e.g., bulging tympanic membrane with loss of normal landmarks, change in color, and poor mobility). Furthermore, both AAP/AAFP and SIGN agree that systemic signs of illness with a MEE or clinical history alone are not sufficient to make a diagnosis of AOM.

Observation of AOM without Treatment

All four guidelines provide a delayed treatment option in which antibacterial treatment of selected children is deferred for 48 to 72 hours. The guidelines differ regarding the subgroups of patients for which this approach should be used in (See "Areas of Differences" below).

Comparison of Recommendations for the Use of Analgesics in Patients with AOM

AAP/AAFP, CCHMC, SIGN, and UMHS all recommend analgesic use in AOM, particularly acetaminophen and ibuprofen (or other non-steroidal anti-inflammatory drugs [NSAIDs*]). The SIGN guideline warns that although NSAIDs* are frequently used by parents, caution should be used because of their side effect profile.

Comparison of Recommendations for Antimicrobial Therapy in Patients with AOM

Amoxicillin as First-Line Therapy. Each of the four guidelines identifies Streptococcus pneumoniae, Haemophilus influenzae, and Moraxella catarrhalis as the most common etiologies for AOM and recommends amoxicillin for first-line therapy (when the use of antibiotics is warranted). SIGN also recommends amoxicillin/clavulanate for first-line therapy. According to AAP/AAFP, the justification to use amoxicillin as first-line therapy in most patients with AOM relates to its general effectiveness when used in sufficient doses against susceptible and intermediate resistant pneumococci, as well as its safety, low cost, acceptable taste, and narrow microbiologic spectrum.

Amoxicillin Dose. The guidelines are in general agreement about the amount of amoxicillin that should be prescribed. AAP/AAFP and CCHMC recommend 80 to 90 mg/kg/day, while UMHS recommends 60 to 90 mg/kg/day. AAP/AAFP's recommendation of 80 to 90 mg/kg/day is based on extrapolation from microbiologic studies and expert opinion, with a preponderance of benefit over risk. The SIGN guidelines do not provide amoxicillin doses, but refer the reader to the British National Formulary.

Duration of Therapy. AAP/AAFP, SIGN, and UMHS indicate that the optimal duration of amoxicillin therapy for patients with AOM has not been established. AAP/AAFP states that several studies that examined outcomes and duration of treatment had significant limitations, including inadequate sample size and lack of age-stratified analyses of outcomes. They note, however, that results of several more recent studies favor 10-day therapy in children younger than 2 years and in children aged 2 to 5 years. The UMHS group reviewed several studies performed prior to the recent increase in penicillin resistance that suggested shorter courses of amoxicillin had efficacy comparable to 10-day courses. However, UMHS also cites a more recent study of amoxicillin/clavulanate that linked 5-day therapy with more frequent recurrence of AOM. The SIGN guideline cites a Cochrane review, which found that 5 days is an effective treatment period for uncomplicated ear infections in children.

In spite of the uncertainty concerning the optimal duration of therapy, the guidelines are in general agreement that a course of 5 to 10 days is appropriate. In addition, AAP/AAFP, CCHMC, and UHMS recommendations are in agreement that children younger than 2 years should receive a 10-day course of therapy. See "Areas of Differences" below, for a discussion of differences in the recommendations concerning children older than 2 years.

Amoxicillin Alternatives. Three guidelines, AAP/AAFP, CCHMC, and UMHS discuss alternative antimicrobials in some detail. The three are in agreement that when amoxicillin is not an appropriate choice (because of allergy, vomiting, or other reasons), second-line antibiotics should be used, such as cephalosporins (including cefdinir, cefuroxime, ceftriaxone). AAP/AAFP and CCHMC also include

macrolides/azalides (azithromycin, clarithromycin), and AAP/AAFP and UMHS include erythromycin-sulfisoxazole or sulfamethoxazole-trimethoprim as options. SIGN does not specifically address the issue of allergy to amoxicillin, but states that cefaclor, cotrimoxazole, trimethoprim, and erythromycin can be effective, but are less safe than amoxicillin. Additional issues related to amoxicillin alternatives are discussed below under "Areas of Differences."

Clinical Failure. For patients initially treated with amoxicillin as first-line therapy who have not improved within 72 hours, AAP/AAFP, CCHMC, and UMHS agree that amoxicillin/clavulanate is the preferred second-line therapy. AAP/AAFP bases its recommendation on observational studies and a preponderance of benefit over risk and states that choice of antibacterial agent should be based on the likely pathogen(s) present and on clinical experience. AAP/AAFP, CCHMC, and UMHS also agree that patients with beta-lactamase producing organisms should be treated with high-dose amoxicillin-clavulanate. SIGN does not specifically address the issue of treatment failure, but in the context of discussing antibiotic therapy states that cefaclor, cotrimoxazole, trimethoprim, and erythromycin can be effective, but are less safe than amoxicillin or amoxicillin/clavulanate.

Comparison of the Use of Patient Education and Preventive Counseling in AOM

While the SIGN guideline makes recommendations concerning prevention of OME, it does not provide specific recommendations concerning prevention of AOM. In contrast, the AAP/AAFP, CCHMC, and UMHS guidelines encourage clinicians to counsel parents concerning preventable risk factors for AOM.

AAP/AAFP, CCHMC, and UMHS agree that day care attendance, pacifier use, and exposure to tobacco smoke significantly increase the risk of AOM. AAP/AAFP states that, during infancy and early childhood, reducing the incidence of respiratory tract infections by altering child care center attendance patterns can significantly reduce the incidence of AOM. For children with recurrent AOM, UMHS encourages discontinuation of pacifier use and recommends the use of xylitol-containing chewing gum. AAP/AAFP and CCHMC include short duration of breastfeeding and bottlefeeding with the child on his/her back as additional preventable risk factors.

AAP/AAFP, CCHMC, and UMHS agree that administration of the pneumococcal conjugate vaccines reduces the risk of ear infections slightly. AAP/AAFP and CCHMC cite a study that showed medical office visits for otitis media were reduced by 7.8% and antibiotic prescriptions by 5.7% in a large clinical practice after administration of the pneumococcal conjugate vaccine. AAP/AAFP and UMHS also suggest influenza vaccine may be useful for the prevention of AOM. According to AAP/AAFP, immunoprophylaxis with killed or live-attenuated intranasal influenza vaccines reduced AOM by 30% during the respiratory illness season in two studies; most of the children in these studies were older than 2 years. A controlled study among infants and toddlers aged 6 to 23 months failed to demonstrate any efficacy of killed vaccine in preventing AOM. AAP/AAFP states that pneumococcal conjugate vaccines have proven effective in preventing vaccine-serotype pneumococcal otitis media, but their overall benefit is small, with only a 6% reduction in the incidence of AOM. CCHMC agrees that the effectiveness of influenza vaccination in preventing AOM remains unclear.

Comparison of Recommendations for Referral

Concerning referral to an audiologist, CCHMC recommends that the practitioner have a low threshold for referral for an audiologic evaluation if concerns around hearing, speech, or language are raised by parents, clinicians, or other caregivers because of recurrent AOM. SIGN recommends referral to an audiologist when audiometry is required for assessment of hearing thresholds and middle ear function. AAP/AAFP and UMHS make no recommendation concerning the need for an audiology referral for AOM patients.

CCHMC, SIGN, and UMHS recommend referral to an otolaryngologist in cases of complicated or persistent AOM. CCHMC recommends referral for recurrent AOM, persistent otorrhea, concerns about mastoiditis or other complications, evaluation for surgery, and an abnormal audiologic evaluation. SIGN identified no studies concerning when AOM patients should be referred and therefore adopts the recommendation of the National Institute for Clinical Excellence (NICE) that children with frequent episodes of AOM (more than four in six months) should be referred to an otolaryngologist. SIGN also recommends referral for complications of AOM such as mastoiditis or facial nerve paresis. The UMHS guideline is more specific than CCHMC and SIGN concerning the type of referral needed. UMHS states an emergent/urgent referral is needed in the case of any suspected complication such as meningitis (medical emergency) or other intracranial complications; facial weakness or paralysis; vertigo; or post-auricular swelling, redness, or displacement of the auricle (mastoiditis). A semi-urgent referral is recommended in cases of failure of antibiotic therapy with persistent severe signs and symptoms of AOM such as high fever or intractable pain (for consideration of diagnostic tympanocentesis). Non-urgent referral should be made for perforation with persistent otorrhea. AAP/AAFP makes no recommendations concerning referrals to an otolaryngologist.

Comparison of Recommendations for the Use of Complementary and Alternative Medicine (CAM) for AOM

UMHS does not address the use of complementary and alternative medicine for AOM. Both AAP/AAFP and SIGN agree that no recommendations can be made due to an absence of evidence of effectiveness in the literature. CCHMC specifically recommends against CAM and certain other therapies to treat AOM. Recognizing that use of CAM is common, however, CCHMC encourages providers to respectfully discuss its safety and efficacy with families who report its use.

Areas of Differences

Observation of AOM without Treatment

Although the guidelines agree that observation without treatment is a recommended approach to AOM, they differ concerning the patient groups to which this option applies. AAP/AAFP and CCHMC use both age and symptom criteria to determine if observation without treatment is appropriate, while UMHS bases the decision primarily on symptoms. SIGN does not limit the option based on either age or symptoms.

AAP/AAFP recommends that deferred treatment can be used in otherwise healthy children aged 6 months to 2 years whose diagnosis is certain or whose diagnosis is uncertain and their illness is non-severe when follow-up can be ensured. AAP/AAFP also recommend this approach for children age 2 years and older with either non-severe illness or an uncertain diagnosis. To support their recommendations, the guideline developers cite studies that compared outcomes associated with initial antibacterial therapy or initial observation.

CCHCM on the other hand, citing two articles by Cohen (1998 and 2000) and the 2004 AAP/AAFP guideline, recommend in general, a 10 day course of antibiotics for children less than 2 years of age, noting that in certain circumstances observation and/or a safety-net antibiotic prescription (SNAP) may be reasonable. For children over age 2 years who are well-appearing, CCHMC recommend that treatment options be discussed with the family. These options include SNAP or a 5-day course of antibiotics

In contrast to AAP/AAFP and CCHMC, the UMHS recommendation is not age-specific but is based on symptoms; observation without treatment is recommended for children with minimally symptomatic AOM. Like CCHMC, UMHS includes the option of providing the parent with a SNAP to be filled within a week at the parent's discretion if symptoms worsen. SIGN on the other hand recommends that in general antibiotics should not be prescribed for the initial management of AOM. Delayed antibiotic treatment (antibiotic to be collected at parents' discretion after 72 hours if child has not improved) is recommended as an alternative approach.

Use of Analgesics other than NSAIDs

While all four guideline developers recommend the use of analgesics, particularly acetaminophen and ibuprofen for the treatment of pain in AOM, they differ in their recommendations about the use of other analgesics. SIGN considered two randomized controlled trials that showed no benefit of oil in reducing pain in AOM and therefore recommended against its use. In contrast, AAP/AAFP noted that home remedies including oil, distraction, and external application of heat or cold may have limited effectiveness although there have been no controlled studies that directly addressed their effectiveness. AAP/AAFP further notes that topical agents including benzocaine and naturopathic agents may provide additional, but brief, benefit over acetaminophen in patients older than 5 years. AAP/AAFP also notes that narcotic analgesia with codeine or analogs is effective for moderate or severe pain. In addition to acetaminophen and ibuprofen, CCHMC also recommends topical ear drops (anesthetic or naturopathic herbal extract), but cautions against their use in patients with a perforated eardrum and/or discharge from the ear, as their use will likely result in severe dizziness and vomiting.

Comparison of Recommendations for the Use of Antimicrobial Therapy in Patients with AOM

Duration of Therapy. As noted above under "Areas of Agreement," AAP/AAFP, CCHMC and UMHS generally agree that a 10 day course of antibiotics is preferred in children under 2 years of age. However, AAP/AAFP differs from CCHMC and UMHS concerning the recommended duration of amoxicillin therapy for children older than 2 years. CCHMC and UMHS recommend that children older than 2 years

receive a 5-day course of therapy, while AAP/AAFP recommends that only children age 6 years and older with mild to moderate disease receive a 5- to 7-day course of therapy; younger children and/or those with severe disease are recommended to receive the standard 10-day course.

Amoxicillin Alternatives. AAP/AAFP and CCHMC recommend ceftriaxone in children with vomiting, whereas UMHS indicates use of ceftriaxone should be limited to situations such as amoxicillin/clavulanate failure or severe systemic symptoms, where parenteral therapy is indicated. UMHS states that while ceftriaxone provides the best-documented coverage of otitis pathogens, concern exists about the potential of this agent to select highly resistant pathogenic bacteria. In addition, patients receiving ceftriaxone should be observed in the office for symptoms of anaphylaxis for at least 15 minutes after administration.

As discussed above under "Areas of Agreement," AAP/AAFP and UMHS, but not CCHMC, include erythromycin-sulfisoxazole and sulfamethoxazole-trimethoprim as acceptable options for children with allergy to amoxicillin. AAP/AAFP states, however, that resistance to erythromycin-sulfisoxazole and sulfamethoxazole-trimethoprim is substantial and use of these agents is not optimal. According to UMHS, macrolides, trimethoprim/sulfa, and most cephalosporins have few advantages over amoxicillin, and in most cases provide inferior coverage. UMHS recommends against macrolides, except azithromycin in the event of amoxicillin allergy, and states that a recent study found a 30% clinical failure rate for azithromycin. In contrast, CCHMC notes that one study showed efficacy and safety with a high dose of azithromycin to treat children with recurrent or persistent AOM.

Some guidelines address topics not addressed by the other guidelines. For example, AAP/AAFP states clindamycin may be used in the penicillin-allergic patient with AOM secondary to penicillin-resistant S. pneumoniae. UMHS notes that topical ofloxacin or ciprofloxacin/hydrocortisone, together with adequate otic toilet, is a valuable adjunct for the treatment of otorrhea and usually obviates the need for systemic antibiotics. Additional discussion concerning approaches to antimicrobial therapy is contained in the original guideline documents of AAP/AAFP, CCHMC, and UMHS.

Note from the National Guideline Clearinghouse: The guidelines in this synthesis reference drugs for which important revised regulatory information has been released.

On April 7, 2005, the U.S. Food and Drug Administration (FDA) asked manufacturers of non-prescription (over the counter [OTC]) non-steroidal anti-inflammatory drugs (NSAIDs) to revise their labeling to include more specific information about potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drugs. See the FDA Web site for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all NSAIDs make labeling changes to their products. FDA recommended proposed labeling for both the prescription and OTC NSAIDs and a medication guide for the entire class of prescription products. See the FDA Web site for more information.

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